DETAILED ACTION

Status of Claims

1. Claims 1 - 11 are pending.

Claims 1 - 11 are rejected.

Claim 10 is objected.

Response to Amendment

2. The amendment to claims 1 and 11, submitted January 20, 2010 is acknowledged and entered.

Claim Objections

3. Claim 10 is objected to because of the following informalities: in line 2 the following is listed "trans-7 CLA". The Examiner notes that in claim 10, submitted with Applicant's respond of September 22, 2008 and entered on December 2, 2008, the following was listed in line 2 of claim 10 "trans -7, trans-9 CLA.. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. The MPEP states that the proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See In re Rasmussen, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). Further, that the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., In re Lukach, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); In re Smith, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads). The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.

7. Claim 11 states: "where in at least about 77% of the fatty acids contained in the total glycerides are a CLA. Applicant refers the Examiner to Table 1 where it shows an amount of CLA of 77.6%. The use of the phrase "at least about" implies some level of tolerance which can imply an amount slightly less or more than 77%. Table 1 only

discloses an amount of 77.6%. Thus, the specification does not support the amendment.

Response to Arguments

8. Applicant's arguments, see page 4, filed January 20, 2010, with respect to 112 first paragraph rejection of claims 1-11 have been fully considered and are persuasive. The 35 USC 112 first paragraph rejection of claims 1-11 has been withdrawn.

9. Applicant's arguments filed January 20, 2010, with respect to the 103(a) rejection of claims 1 – 11 Krumhar (US 6,432,453) in view of Koike et al. (WO 2002/11552 A2) and further in view of Cain et al. (US 6,184,009) have been fully considered but they are not persuasive, for the reasons set out in the Office Action mailed July 21, 2009 and as set out below.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1- 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krumhar (US 6,432,453) in view of Koike et al. (WO 2002/11552 A2) and further in view of Cain et al. (US 6,184,009).

14. The rejected claims cover, inter alia, an oil composition comprising about 80-95% by weight of diglycerides, wherein about 50-95% of the fatty acids contained in the total glycerides are a conjugated linoleic acid (CLA).

15. Krumhar teaches compositions comprising glycerol esters of conjugated linoleic acid, wherein the glycerol esters are selected from the group consisting of monoglyceride, diglyceride, triglyceride and mixtures thereof (abstract, column 4, lines 7-8). The CLA esters of Krumhar can be used in dietary supplements, foods and drugs. (see column3, lines 65-67). Also, Krumhar teaches various methods of preparing the diglycerides of conjugated linoleic acid such as transesterification, or via acid by reacting CLA and glycerol from a mixture of cis-9, trans-11 CLA and trans-10, cis12 CLA (see column 5, lines 25-41). Further, Krumhar discloses that the CLA

glycerol ester is provided in the dietary supplements from about 32% to about 91% by weight of the conjugated linoleic acid (see claim 1 & col. 6 Table 1 and liens 10 - 12), and that the glycerol ester is selected from the group consisting of monoglyceride, diglyceride triglyceride and mixtures thereof (see claim 2). Krumhar discloses that the composition can contain glycerol. (see column 5, lines 63-64, & Table 1). Krumhar discloses that CLA is a naturally occurring group of dienoic derivatives of linoleic acid found in the fat of beef and other ruminants. (see column 1, liens 21 - 22).

16. The difference between Krumhar and Applicant's claimed invention is the following: specific percentages of the diglyceride; the oil source of the CLA; the specific foods that may include CLA; the specific form of the pharmaceutical containing CLA and the various isomeric formations of CLA in the triglyceride.

17. However, Koike et al. discloses a oil/fat composition teaches a fat composition comprising 60-100% of a diglyceride (DG) (see abstract). Table 1 teaches examples where the DG is present in an amount greater than 85%, triglyceride (TG) is 13.4-15.6, monoglyceride (MG) is 1.1-3.1 and fatty acid C18:2 (w6)(c-10, c-12) is 16.4-17.5. Table 5 teaches another example of DG greater than 85% and that the conjugated amount is 16.4% (c-19, c-12). Further, the oil/fat composition of Koike et al. prepares the oil composition from natural oils such as linseed oil and rapeseed. (see Composition 2 page 17). The composition of Koike et al. can be used in foods such as, dressings, mayonnaise, whipped cram, ice cream, margarine, spread, butter cream and edible oils (see page 11, lines 13-22; page 12, line 13). Also, when used in a pharmaceutical

composition, it can be in the form of a powder, capsule, tablet or liquid. (see page 15, liens 19-20). Furthermore, it can be added to feed. (see page 16, line 10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Krumhar in view of Koike et al. Krumhar generically teaches a composition of mono-, di- and tri-glycerides including CLA in the percentages as instantly claimed, while Koike et al. teaches the percentage of the diglyceride in such a composition. One of ordinary skill in the art would have been motivated to combine since all teach fat compositions comprising a mixture of glycerides including diglycerides for food, pharmaceutical and feed additive with Koike et al. teaching the percentage of diglycerides and Krumhar teaches the cis-9, trans-11 CLA and trans-10, cis12 CLA mixture contains diglycerides. One of ordinary skill in the art would have a reasonable expectation of success in formulating the composition of 'Krumhar in view of Koike et al since both teach the same components in a fat composition for food supplementation and pharmaceuticals. The product of Krumhar containing CLA diglycerides could easily be made by the skilled artisan in the amounts instant claimed using a known techniques and preferred ranges taught by Koike et al.

18. With regard to the oil source of the CLA, and the various isomeric formations of CLA in the triglyceride the Examiner turned to the teachings of Cain et al. The Cain et al. reference teaches a process for preparing a material containing the geometrical isomers of conjugated linoleic acid moieties in specific weight ratios. The starting material is fish oil or vegetable oil and the products may be blended with complementary fat, used as food or food supplements or in pharmaceutical

compositions. (see abstract). Further, Cain states the following in column 1, at lines 19-26.

> Because of cis/trans-isomerism above CLA's can contain 8 different isomers, i.e. cis^{9}-cis^{11}; cis^{9}-$trans^{11}$; $trans^{9}$-cis^{11}; $trans^{9}$-$trans^{11}$; cis^{10}-cis^{12}; cis^{10}-$trans^{12}$; $trans^{10}$-cis^{12} and $trans^{10}$-$trans^{12}$. From those isomers the cis^{9}-$trans^{11}$ and $trans^{10}$-cis^{12} are the most abundant, while their concentrations are about equal. It is generally believed, that those two most abundant isomers are responsible for the beneficial effects of the compositions, containing CLA's.

19. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have an oil composition produced from natural products contain conjugated linoleic acid (CLA) with varied isometric structures, as suggested by Cain et al.; because according to the teachings of Cain, CLA's have 8 different isomeric forms. Further, one having ordinary skill in the are would be able to produce such an oil composition containing a mixture of these isomeric forms, as claimed by Applicant, since Cain suggest a process for preparing the geometric isomers of CLA using a protein that is capable of effecting the transformation of linoleic acid to the desired forms. One of ordinary skill in the art would have been motivated to produce an oil composition with different isomeric forms of CLA because Krumhar and Cain et al. each suggest the use of CLAs for use in foods, food supplements and pharmaceuticals (drugs).

Therefore, based on the references set out above, and the teachings therein, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Response to Arguments

20. Applicant respectfully asserts that the Krumhar reference does not direct a person having ordinary skill in the art to make a composition containing 89 to 95% diglycerides because it does not indicate the percent of each glyceride should be included in their composition. Further, Applicant asserts that this is not cured by Koike et al. because their diglycerides include high percentage of linolenic acid. Lastly, Cain does not cure the deficiencies of Krumhar and Koike et al. because it does not direct one having ordinary skill in the art to make the claimed composition.

21. In response, the Examiner states that the arts of Krumhar and Koike et al. are directed to fatty compositions containing mixtures of mono, di and triglycerides and therefore analogous. Koike et al. is relied on to show that compositions of high diglyceride content are known and can be easily produced by skilled artisan and that the generic teaching of Krumhar or of cis-9, trans-11 CLA and trans-10 and cis-12 CLA mixture is also known by the skilled artisan. As such the same technique for obtaining the high purity diglyceride formulation of Koike et al. in the compositions advanced by Krumhar would therefore not be beyond the purview of the skilled artisan.

22. Also, Applicant asserts that Krumhar states that triglycerides are preferred.

23. In response, the Examiner points out that Krumhar generically claims the same composition as instantly claimed. A patent of the instant claims would read on the claims of Krumhar, which teaches an oil composition comprising a mixture of mono, di and triglycerides of conjugated linoleic acid. Thus, the claims are generically directed to the same oil composition invention of Krumhar and in combination with Koike et al. the

skilled artisan would know how to obtain a high diglyceride percent composition. The art relied upon teaches that the ranges as instantly claimed are not novel or unobvious but in fact that the diglyceride ranges are known and used in other fat compositions.

24. With regard to Cain, the Examiner used this reference to show that it was well known in the art by the skilled artisan that CLA can be derived from natural animal and vegetable sources. Also, that it was well known in the art at the time of Applicant's claimed invention that CLA has 8 different isomers and the methods for preparing the desired isomers were within the purview of the skilled artisan. It is well settled that a patent cannot be properly granted for the discovery of a result which would flow naturally from the teaching of the prior art. In re Libby, 118, USPQ 94, 96; 255 F2d 412 (C.C.P.A. 1958).

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YATE' K. CUTLIFF whose telephone number is (571)272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on (571) 272 - 0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Yaté K. Cutliff/
Patent Examiner
Group Art Unit 1621
Technology Center 1600

/Daniel M Sullivan/
Supervisory Patent Examiner, Art Unit 1621